K110631

JUL 28 2011

SUMMARY OF SAFETY AND EFFECTIVENESS

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

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1.2 Official Correspondent

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1.3 Date of Preparation

February 25, 2011

2 NAME OF THE DEVICE

2.1 Trade/Proprietary Name

Venner™ Tracheal Seal Monitor

2.2 Common/Usual Name

Cuff pressure regulator and monitor

2.3 Classification Information

Classification Name: Inflatable Tracheal Tube Cuff

Classification Regulation: 21 CFR § 868.5750

Class: II

Product Code: BSK

Panel: Anesthesiology

3 PREDICATE DEVICES

The predicate devices are as follows:

1) the Lanz Pressure Valve cleared under premarket notification K885216; and,

2) the PYTON Cuff Pressure Regulator cleared under premarket notification K092733.

The predicate devices are cuff pressure regulators, have been cleared by FDA and classified under 21 CFR § 868.5750, as Class II medical devices.

4 DESCRIPTION OF THE DEVICE

The Venner™ Tracheal Seal Monitor consists of an automatic inflation cuff controller (control unit) that connects to the Venner™ PneuX P.Y.™ Endotracheal or Tracheostomy Tube using a single patient use, sterile extension tube. The Venner™ Tracheal Seal Monitor regulates and maintains cuff pressure in endotracheal and tracheostomy tubes in adult patients in the intensive care unit (ICU) setting. The device is intended to measure, monitor and maintain a stable cuff pressure in endotracheal and tracheostomy tubes.

During intubation, variations in cuff pressure may occur for multiple reasons, including the transfusion of gases through the cuff, changes in tracheal compliance, modifications in the location of the cuff within the airway, and other reasons. Maintaining a consistent and stable cuff pressure is intended to help minimize complications, such as excessive tracheal wall pressure that may lead to necrosis, and problems associated with inadequate tracheal wall pressure, such as aspiration pneumonia.

The Venner™ Tracheal Seal Monitor consists of an electronic automatic pressure controller with a pressure sensors and a pump, and provides a user interface with adjustable settings, indicators and alarms. The Venner Tracheal Seal Monitor is intended to be used with the following commercially available devices:

1. The Venner™ PneuX P.Y.™ Endotracheal Tube: This endotracheal tube was cleared by FDA under premarket notification K093135. It is a straight, cuffed, wire reinforced tracheal tube. It is packaged separately and provided as a sterile, single use device.

2. The Venner™ PneuX P.Y.™ Tracheostomy Tube: The tracheostomy tube was cleared by FDA under premarket notification K100950. It is a straight, flexible, cuffed tracheostomy tube with an adjustable neck plate. It is packaged separately and provided as a sterile, single use device.

3. Extension Tube: The extension tube is a class I, medical device exempt from premarket notification under 21 CFR § 868.5860. The extension tube connects the Venner Tracheal Seal Monitor to the cuff of an endotracheal or tracheostomy tube. It uses a non-luer connector at the proximal end to connect to the control unit and a patented luer slip connector at the distal end with a unique design feature to prevent

accidental misconnection of the air line to a standard luer lock connector (i.e., standard infusion sets and catheters with female lugged luer lock connectors). It is packaged separately and provided as a sterile, single patient use device.

5 INDICATIONS FOR USE AND INTENDED USE

The Venner™ Tracheal Seal Monitor has the following indications for use:

> *"The Venner™ Tracheal Seal Monitor (TSM) is indicated for use to monitor, maintain and regulate the pressure within the PneuX P.Y.™ Endotracheal or Tracheostomy Tube Cuff in adult patients who have been confined to hospital ICU units where intubation is expected to be more than 24 hours, but less than or equal to 30 days."*

This is the same intended use as the predicate devices.

The Venner™ Tracheal Seal Monitor and the predicate devices share the same intended use – namely, to maintain and regulate pressure in the cuffs of endotracheal and tracheostomy tubes in patients who require intubation. Two of the devices (the Venner™ Tracheal Seal Monitor and the PYTON Cuff Pressure Regulator) also measure and monitor cuff pressure.

Each device is intended to ensure proper inflation of the cuff to provide a seal between the airway tube and the patient's trachea by maintaining and regulating cuff pressure.
The Venner™ Tracheal Seal Monitor and the predicate devices all share the same primary function; that is, to obtain a cuff-to-tracheal seal pressure of approximately 25-30 cm H_2O to ensure that the cuff provides a proper seal between the tube and the patient's trachea to prevent the leakage of liquids and risk of aspiration, and to minimize the risk of over-pressure and damage to the trachea. The devices are intended for use for the same patient population: patients who require intubation. The table on the following page establishes the Venner™ Tracheal Seal Monitor and the predicate devices have the same intended use.

A Comparison of the Venner™ Tracheal Seal Monitor to the Predicate Devices

Device Characteristic	Venner™ Tracheal Seal Monitor and Extension Tube	Lanz Pressure Valve Mallinckrodt, Inc. K885216[1]	PYTON Cuff Pressure Regulator ARM Medical Devices, Inc. K092733[2]
Indications for Use	… is indicated for use to monitor, maintain and regulate the pressure within the PneuX P.Y.™ Endotracheal or Tracheostomy Tube Cuff in adult patients who have been confined to hospital ICU units where intubation is expected to be more than 24 hours, but less than or equal to 30 days	… is indicated for use with cuffed tracheal and tracheostomy tubes when intracuff pressures of approximately 30 cm H_2O are judged by the clinician to be appropriate	…to measure and regulate intra-cuff pressures of endotracheal supraglottic airways or tracheostomy tubes…for patients who are intubated…in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics…
Intended Use	To regulate and maintain cuff pressure To measure and monitor cuff pressure	To regulate and maintain cuff pressure	To regulate and maintain cuff pressure To measure and monitor cuff pressure
Intended Patient Population	Adult patients requiring intubation	Patients requiring intubation	Patients requiring intubation
Intended Users	Prescription device – healthcare professionals	Prescription device – healthcare professionals	Prescription device – healthcare professionals
Operational Environment	Intensive care units (ICU)	Unspecified	Multiple settings where a patient may be intubated, including the ICU
Primary Device Functions	To continuously measure cuff pressure To regulate and maintain cuff pressure	To regulate and maintain cuff pressure	To continuously measure cuff pressure To regulate and maintain cuff pressure
Cuff-Tracheal Seal Pressure Range	Default: 30 cm H_2O (22 mmHg) Range: 10 – 50 mmHg in 10 mmHg intervals	Recommended setting: 30 cm H_2O	Default: 25 cm H_2O Range: 0 – 85 cm H_2O
Pressure Monitor and Control Mechanisms	Control unit consists of an electronic, software-driven device with pressure sensors and stepping motor to adjust pressure	Elastic balloon aids in regulating pressure by expanding and contracting	Control unit consists of an electronic, software-driven device with pressure sensors and pump to adjust pressure
Pressure Accuracy	± 5% of set value	Not available	± 2.0 cm H_2O
System Components	Control unit (capital equipment) Extension tube (single patient use) to connect control unit to endotracheal or tracheostomy tube	Single patient use device attached to the endotracheal or tracheostomy tube	Control unit (capital equipment) Plastic tubing set (single patient use) to connect control unit to endotracheal or tracheostomy tube
User Interface	Digital display with cuff pressure and pushbuttons	Visual inspection of balloon	LED back-lit LCD digital display with cuff pressure and pushbuttons

[1] Information obtained from the purged 510(k) application K885216.
[2] Information obtained from the 510(k) Summary for K092733 dated February 26, 2010.

Device Characteristic	Venner™ Tracheal Seal Monitor and Extension Tube	Lanz Pressure Valve Mallinckrodt, Inc. K885216[1]	PYTON Cuff Pressure Regulator ARM Medical Devices, Inc. K092733[2]
Alarms	Multiple alarms, including alarms for pressure, air leak, malposition, blockage	One alarm when pressure exceeds 25 cm H_2O	Yes although details not provided
Safety Valve	Incorporates a pressure relief valve if cuff-tracheal seal pressure were to exceed 57 mmHg	No	Incorporates a pressure relief valve if cuff-tracheal seal pressure were to exceed 100 cm H_2O
Power source	Electrical	Manual	Electrical with battery backup

6 TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The Venner™ Tracheal Seal Monitor and the predicate devices share many of the same technological characteristics as summarized in the previous table. All of the devices share the same primary function: that is, to obtain a cuff-to-tracheal seal pressure of approximately 25-30 cm H_2O to ensure that the cuff provides a proper seal between the tube and the patient's trachea to prevent the leakage of liquids and risk of aspiration, and to minimize the risk of over-pressure and damage to the trachea.

Two of the devices (the Venner™ Tracheal Seal Monitor and the PYTON Cuff Pressure Regulator) accomplish this goal by using a software-based, electro-mechanical control unit with similar accuracies in their measurements and other features, including alarms, indicators and safety features. Please refer to the table for additional details.

7 PERFORMANCE TESTING

The 510(k) submission provided performance data to establish the substantial equivalence of the Venner™ Tracheal Seal Monitor to the predicate devices. Performance testing was performed to demonstrate that the Venner™ Tracheal Seal Monitor met its specifications, and is suitable and ready for commercial distribution.

These tests evaluated the ability of the Venner™ Tracheal Seal Monitor to maintain and regulate cuff pressure in a variety of settings, and often compared its performance to other devices. These studies established the accuracy the Venner™ Tracheal Seal Monitor to maintain the selected pressure; the device met its specified accuracy of ± 5%. Other studies evaluated the ability of the Venner™ Tracheal Seal Monitor to regulate and maintain cuff pressure in a variety of physical settings, and the reaction time of the device to change the pressure in the cuff. In each study, the Venner™ Tracheal Seal Monitor was able to maintain and regulate the pressure of a cuff of an airway tube, and to quickly adapt to changes in the environment or changes programmed by the user. These studies also evaluated the performance of the safety over-pressure valve to demonstrate that the valve automatically opened with an audible "click" when the calculated cuff-tracheal seal wall pressure exceeded 57 mm Hg, and subsequently closed (or reset) when the calculated cuff-tracheal seal wall pressure returned to 27 mm Hg for safe operation. The safety valve performed within specifications and met the acceptance criteria.

The Venner™ Tracheal Seal Monitor underwent system level software verification and validation testing to demonstrate the device performs as intended, and meets its requirements. The device passed all testing and met its specifications.

The Venner™ Tracheal Seal Monitor met international safety standards, including electrical and electromagnetic safety testing (EN 60601-1, 60601-2 and 60601-4).

The sponsor also performed a series of tests to demonstrate that its device can withstand exposure to environmental stresses (i.e., random vibration, sinusoidal vibration and bump) and continue to perform as intended. In these studies, the Venner Tracheal Seal Monitor was

tested according to the following standards: IEC 60068-2-64: Random Vibration, IEC 60068-2-6: Sinusoidal Vibration; IEC 60068-2-64: Random Vibration; and IEC 60068-2-27: Bump. The device successfully completed the testing.

8 CONCLUSIONS

This 510(k) submission demonstrates that the Venner™ Tracheal Seal Monitor is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 28 2011

Re: K110631
Trade/Device Name: Venner™ Tracheal Seal Monitor
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: II
Product Code: BSK
Dated: June 22, 2011
Received: June 24, 2011

Dear Dr. Brauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDR /CDRHOffices/ucm1 5809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Venner™ Tracheal Seal Monitor

Indications for Use:

The Venner™ Tracheal Seal Monitor (TSM) is indicated for use to monitor, maintain and regulate the pressure within the PneuX P.Y.™ Endotracheal or Tracheostomy Tube Cuff in adult patients who have been confined to hospital ICU units where intubation is expected to be more than 24 hours, but less than or equal to 30 days.

Prescription Use __x_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110631